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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,117	04/02/2004	Ruben G. Carbonell	51821-0111 (51821-299533)	3952

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EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,117	CARBONELL ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,9-33 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,9-33 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 7, 2007 has been entered.

Claims 1, 14, and 15 have been amended. Claims 7, 8, and 34-49 have been canceled. Claims 1, 2, 5, 8, 9-33, and 50-54 are under examination.

Claim Rejections - 35 USC § 112

The rejection of claims 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants amended the claims to recite chemical formulas. The recited formulas are not found in the specification. If the chemical formulas recited in the claims represent the products of previously recited trademarks such as FRACTOGEL EMD, TOYOPEARL, or TSK GEL, Applicants are required to amend the specification to introduce the recited chemical formulas that find support in the specification. Applicant is also required to point out which trademark name corresponds with which chemical formula.

Claims 1, 2, 5, 8, 9-33, and 50-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of forming a complex between a prion protein and a prion protein binding material using an affinity resin such as for example Toyopearl 650 M amino resin and a number of other resins listed in Tables 1 and 3 (that have shown positive binding results), does not reasonably provide enablement for methods of using any affinity amino resin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims read on methods of removing prions from a sample by contacting the sample with an amino resin.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of

those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. In the present case, the factors deemed relevant are those of the amount of direction and the working examples provided, that quantity of experimentation necessary, the (un)predictability of the art, and the breadth of the claims.

In this case, the relevant factors to be considered are the number of examples provided, the scope of the claims, and the guidance presented in the application.

The specification discloses a few instances where an amino resin was capable of binding to prion proteins in a sample. Specifically the Toyopearl Amino-650M was successfully used for binding and removal of prion proteins from the sample (see Example 2 and Tables 1 and 3).

Tables 1 and 3 of the specification, provide evidence that many of the other tested affinity resins such as for example Toyopearl AF-Carboxy-650M did not bind prion proteins at all. While the claims are broadly drawn to methods of using any affinity amino resin, the teachings of the specification are limited to a specific resin, and provide no guidance towards any affinity amino resins that would be useful in the claimed methods.

It is noted that the art does not provide many teachings about the use of unmodified resins for the specific capture of prions. However, one reference (Carbonell et al., U.S. 2005/0014196) does provide teachings indicating that not every resin would be useful in the claimed methods. See e.g., pages 9-11 (Table I- showing that some resins do, and others do not, bind prions). In particular, while the reference supports the teachings of the present application with respect to the Toyopearl® 650M amino resin, other amino resins disclosed in the reference did not bind to prions. See e.g., Page 10, Reference 46 (teaching that the E. Merck Fractogel ® EMD Amino

resin was not effective for bind prions). In view of these teachings indicating that not every affinity amino resin would be capable of use in the claimed methods, and in view of the limited teachings in the present application providing guidance to amino resins that would be so useful other than the single embodiment disclosed, the application has not provided sufficient information to enable those in the art to practice the claimed method to the full extent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claims 1, 2, 5, 6, and 9-33, 50-52 and new claim 54 under 35 USC 102(b) as being anticipated by Foster et al., (2000, Vox Sanguinis Vol. 78, p. 86-95) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS) **is maintained.**

Applicants' arguments have been fully considered but fail to persuade. Applicants amended the claims to recite, "(...) wherein the polymer matrix is an affinity resin".

Applicants argue that the Foster does not teach the use of a polymer matrix that is an affinity resin and is capable of binding specifically and selectively to the prion protein as claimed. Applicants argue that the polymer matrix of the present invention and the polymer matrix disclosed by Foster have different structures. Particularly the polymer matrix of the present invention is Toyopearl amino 650M, which is an affinity resin, and the polymer matrix of

Foster is a DEAE Toyopearl 650M, which is an ion exchange resin. Applicant provides chemical structures of the two different resins as well as affidavits containing data sheet for resins produced by Tosoh. Applicants also argue that when the Applicants compared the two different resins the prion binding obtained using Toyopearl amino 650M was stronger (+++) than the prion binding obtained using DEAE Toyopearl 650M (+).

Applicants' arguments are not persuasive for the following reasons. Applicants argue limitations (Toyopearl amino 650M) that are not recited in the claims. The affinity resin recited in claim 1 is not defined in the specification. Thus under broadest reasonable interpretation it is determined that an ion exchange disclosed by Foster, can be regarded as an affinity resin because of the affinity interactions formed between positive and negative charges of cations and anions formed in an ion exchanger. Furthermore claims 12 and 14 that depend from claim 1, recite structures that are defined by the Applicant (see Remarks page 11) and by the affidavits submitted by the Applicant, as the structures used for an ion/anion exchange. Thus in the absence of the definition in the specification with regard to the recited "affinity resin" it is interpreted that an "affinity resin" encompasses the ion exchange resin. Thus by teaching a method of using an ion exchange resin Foster anticipates the current claims. The fact that Foster's DEAE Toyopearl 650M did not work as well as Toyopearl amino 650M is irrelevant, because Foster's affinity resin was successfully used to remove prions from a sample, albeit with a different efficiency. For the above reasons the rejection is maintained.

New claim 54 is drawn to the method of claim 1 wherein the polymer comprises a polymeric backbone covalently attached to the functional group. Foster anticipates this limitation in that Foster's DEAE Toyopearl 650M comprises a polymeric backbone covalently attached to

the functional group as evidenced by Data sheet of record of 6/20/2006 and Data sheet for Tosoh products submitted by the Applicant.

Rejection of claims 1, 2, 5, 6, 9-33 under 35 U.S.C. 102(e) as being anticipated by Hammond et al., (U.S. 6,750,025) **is withdrawn** in view of Applicant's arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claims 1, 2, 5, 6, and 9-33 and new claims 53 and 54 under 103(a) as being unpatentable over Pruisner (US Patent 6,221,614 B1) in view of Kragten et al., (1998, J Biol Chem 273: 5821-28) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS) **is maintained**.

Applicants arguments have been fully considered but fail to persuade. In response to applicant's argument that the reference by Kragten is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kragten teaches the method for

affinity precipitation of proteins using a polymer matrix such as Toyopearl AF amino 650M. Kargten also teaches that Toyopearl AF amino 650M is a commonly used substrate for protein purification. The fact that Kragten does not specifically teach using Toyopearl AF amino 650M for affinity purification of prion proteins is not essential, because Kragten by his teachings provides a motivation to one of ordinary skill in the to use Toyopearl AF amino 650M for precipitation of other proteins such as for example prion proteins taught by Prusiner. Thus it is Examiners position that references by Prusiner and Kragten are combinable and their combination renders the present invention obvious to one of ordinary skill in the art. Therefore the rejection is maintained.

With regard to limitations of claims 53, because Kragten teaches a polymer matrix that is not an ion exchange matrix, Kragten teaches the limitation of claim 53. Kragten's Toyopearl AF amino 650M is an affinity matrix as evidenced by Data sheet for Tosoh products submitted by the Applicants. New claim 54 is drawn to the method of claim 1 wherein the polymer comprises a polymeric backbone covalently attached to the functional group. Kragten teaches this limitation in that Kragten's Toyopearl AF amino 650M comprises a polymeric backbone covalently attached to the functional group as evidenced by Data sheet of record of 6/20/2006 and Data sheet for Tosoh products submitted by the Applicant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Rejection of claims 1, 2, 5, 6 and 8-33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/962, 670 **is maintained.**

Applicants argue that the rejection should be withdrawn in view of the amendment to the claims in the present and in the copending Application. It is noted that the amendment to the claims of the present Applications does not remove the obviousness of the current claims over claims of the copending Application.

Claims 1-6 and 8-33 of the instant application are drawn to a method of forming and detecting a complex between a prion protein and prion protein binding material. Claims 1-20 of the reference application are drawn to a method of detecting and separating prion protein from a sample comprising contacting the sample with a polymeric prion protein binding material. The prion binding material both the instant and the reference application is a Toyopearl™ amino 650, a polymer matrix bound to an amine group.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are generic to the present claims. The limitations of the present claims are inherent to the copending claims (i.e. forming and detecting

a complex between a prion protein and a prion protein binding material). The present claims are therefore obvious variations of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on M-F from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 6-20-2007 Primary Examiner, TC1600